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ARENT FOX PLLC  
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WASHINGTON, DC 20036

EXAMINER
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EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
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1734

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08/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/542,954

Applicant(s)

TREBBI, ROBERTO

Examiner

Laura Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

***Specification***

The abstract of the disclosure is objected to because it should be on a single clean sheet by itself. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

Claims 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17, lines 1-2, "the access conduit" lacks antecedent basis.

In claim 19, lines 1-2, "the access conduit" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al (EP 0362888).

Itoh et al provide a coating apparatus capable of treatment of granulate materials including pharmaceutical products (col. 1, lines 16-22) comprising a pan (1) that revolves about an axis of rotation and a dispensing unit (11) designed to disperse a coating material inside the pan over a mass of the products located in the pan; the machine being characterised in that the

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pan has an opening (11) for feeding the products to be treated into the pan, and an opening (31) for feeding the products already treated with the coating material out of the pan, the infeed opening and the outfeed opening being separate and independent of each other; a portion of the inside surface of the pan being equipped with at least one helical flow regulating fin (15) designed to facilitate inflow of the products to be treated into the pan during the feeding of the products into the pan through the infeed opening when the pan itself revolves in a first direction of rotation (A), and to cause outflow of the treated products from the pan during the outfeed of the treated products from the pan through the outfeed opening when the pan itself revolves in a second direction of rotation (B), opposite to the first direction of rotation.

With respect to claim 3, see col. 4, lines 35-48 wherein guide means used in association with the regulating fin is triangular in form. Also see col. 6, lines 11-16 wherein the shaping or profiling of the regulating fin can be varied.

With respect to claim 4, see col. 8, lines 28 to 43 wherein the outfeed opening there is connected a wall of the drum to a chute guide element (31) connected to a collecting reservoir (not shown).

With respect to claim 9, see tubular conduit (31) made on a mouth portion (12) or protrusion of the drum.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Velo (EP 0504773).

Velo provides a coating apparatus capable of treatment of granulate materials including pharmaceutical products (col. 1, lines 1-10) comprising a pan or drum (5) that revolves about an

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axis of rotation and a conventional dispensing unit (not shown) to disperse coating material inside the pan over a mass of the products located in the pan; the machine being characterised in that the pan has an opening (18) for feeding the products to be treated into the pan, and an opening (17) for feeding the products already treated with the coating material out of the pan, the infeed opening and the outfeed opening being separate and independent of each other; a portion of the inside surface of the pan being equipped with at least one helical flow regulating fin (19) designed to facilitate inflow of the products to be treated into the pan during the feeding of the products into the pan through the infeed opening when the pan itself revolves in a first direction of rotation (counterclockwise), and to cause outflow of the treated products from the pan during the outfeed of the treated products from the pan through the outfeed opening when the pan itself revolves in a second direction of rotation (clockwise), opposite to the first direction of rotation (col. 3, lines 10-27).

With respect to claim 3, see Fig. 1 wherein the blade has a pointed edge and a base connected to the inner wall of the drum and see col. 4, lines 4-10 wherein the blades can be in any shape.

With respect to claim 4, see blade having a first end (20) and second end (21) defining a chute guide element at the outlet of the drum.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al (EP 0362888) in view of Velo (EP 0504773).

The teachings of Itoh et al have been mentioned above but Itoh et al do not disclose a plurality of spaced flow regulating fins. However, it was known in the art, at the time the invention was made, to provide spaced flow regulating fins (19) disposed internally from one end of a panning drum to an opposite end to allow for internal mixing and coating of pills or tablets with coating material as evidenced by Velo (col. 2, lines 24-29; col. 3, lines 11-27). In light of the teachings of Velo, it would have been obvious to one of ordinary skill in the art to provide plural spaced flow regulating fins internally of rotary pan of Itoh et al, from one end to the other, in order to facilitate internal mixing and coating of pills or tablets with coating material. With respect to the equal spacing of the flow regulating fins, it is within the purview of one skilled in the art to equally space the fins along the pan's interior in order to effect uniformity in mixing and/or coating of the pills or tablets.

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Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al (EP 0362888) in view of Velo (EP 0504773) as applied to claim 5 above, and further in view of Burke et al (US 6,769,381).

The teachings of Itoh et al and Burke et al have been mentioned above but neither teach or suggest angularly spaced chute like guide elements at the outfeed opening. However, it was known in the art, at the time the invention was made, to provide a plurality of predetermined angularly spaced chute like guide elements (84, 85, 86) at the outfeed opening in order to promote reverse tumbling or mixing of materials within the rotary drum or pan with minimal product breakage as evidenced by Burke et al (col. 12, lines 8-31). It would have been obvious to one of ordinary skill in the art to provide predetermined angularly spaced chute like guide elements as taught by Burke et al in the apparatus defined by the combination above in order to promote reverse tumbling/mixing of the pills or tablets with coating material with minimal breakage of the pills or tablets. Moreover, the use of an appropriate number of chute like elements is within the purview of one skilled in the art to facilitate the tumbling/mixing action.

With respect to the angular intervals between the guide elements being 120 degrees, Burke et al allude to the angular disposition of the guide elements within the rotary drum contributing to more or less tumbling such that one of ordinary skill in the art would determine via experimentation the angular disposition of the guide elements in accordance with the degree of tumbling action required.

Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al (EP 0362888) in view of Blouin (T927005).

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The teachings of Itoh et al have been mentioned above and while an access conduit (8) is provided on a protrusion of the pan, the conduit (8) being accessible from outside, Itoh et al are silent concerning an inclined surface that extends therefrom. However, it was known in the art, at the time the invention was made, to provide an inclined surface or inclined chute from an accessible conduit as a means to feed particulate materials into a rotary drum or pan as evidenced by Blounin (Fig. 2, conduit (6) to angled chute (area above element 16)). It would have been obvious to one of ordinary skill in the art to provide an inclined surface of chute as taught by Blouin in communication with the access conduit of the Itoh et al as a means to feed the pills or tablets into the pan or drum.

With respect to claim 12, Itoh et al provide an outfeed reservoir as evidenced by col. 8, lines 39-44. Itoh et al are silent concerning an infeed reservoir but it was known in the art at the time the invention was made, to provide an infeed reservoir (2) or hopper to provide for a supply of material into a pan or drum as evidenced by Blouin (See Fig. 2). One of ordinary skill in the art would readily appreciate the provision of an infeed reservoir or hopper as taught by Blouin connected to the infeed opening or access conduit 8 of Itoh et al in order to provide for a supply of pills or tablets or coating material to the drum or pan.

Claims 10 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al (EP 0362888) in view of Dunn Jr. (US 3,606,860) and Gross (US 4,421,020).

The teachings of Itoh et al have been mentioned above but Itoh et al fail to teach or suggest a sealed shutoff valve on the tubular outlet conduit or inlet/access conduit. However, it was known in the art, at the time the invention was made, to provide sealed valving on the inlet



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and outlet conduits of a pan or drum to control the flow of material therethrough as evidenced by Dunn, Jr. (col. 2, lines 52-58 and col. 3, lines 4-5) and it was known to utilize shutoff valving on inlet and outlet conduits of a drum to control flow or non-flow of material with respect to a drum as evidenced by Gross (col. 6, lines 38-44 and col. 7, lines 45-48). In light of the teachings of both Dunn Jr. and Gross, it would have been within the purview of one skilled in the art to provide valving of the shutoff type on the inlet and outlet conduits to the pan or drum of Itoh et al in order to control flow of material introduced into and out from the pan or drum.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al (EP 0362888) and Blouin (T927005) as applied to claim 8 above, and further in view of Dunn Jr. (US 3,606,860) and Gross (US 4,421,020).

The teachings of Itoh et al and Blouin have been mentioned above but neither teach or suggest a sealed shutoff valve on the tubular outlet conduit or inlet/access conduit. However, it was known in the art, at the time the invention was made, to provide sealed valving on the inlet and outlet conduits of a pan or drum to control the flow of material therethrough as evidenced by Dunn, Jr. (col. 2, lines 52-58 and col. 3, lines 4-5) and it was known to utilize shutoff valving on inlet and outlet conduits of a drum to control flow or non-flow of material with respect to a drum as evidenced by Gross (col. 6, lines 38-44 and col. 7, lines 45-48). In light of the teachings of both Dunn Jr. and Gross, it would have been within the purview of one skilled in the art to provide valving of the shutoff type on the inlet and outlet conduits to the pan or drum of the apparatus defined by the combination above in order to control flow of material introduced into and out from the pan or drum.

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Claims 2, 9, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) in view of Itoh et al (EP 0362888).

The teachings of Velo have been mentioned above but Velo is silent concerning the infeed opening in the pan being at a position above and to one side of the outfeed opening. However, it was known in the art at the time the invention was made, to arrange in a pan coating apparatus, an infeed opening in the pan being at a position above and to one side of the outfeed opening as evidenced by Itoh et al (see Fig. 3, inlet (8) and outlet (31)). In light of the arrangement of Itoh et al, one of ordinary skill in the art would readily appreciate arranging of the infeed opening in the pan being at a position above and to one side of the outfeed opening as an alternate supply and removal arrangement for the pills or tablets.

With respect to claim 9, Velo is silent concerning the outfeed opening comprising a tubular conduit leading to the outside of the pan. However, it was known in the art at the time the invention was made, to provide a tubular conduit or inclined chute (31) connected to the outfeed opening of a pan to direct the coated material out of the drum to a desired location as evidenced by Itoh et al (Fig. 3). One of ordinary skill in the art would expect to provide a chute or inclined tubular conduit to direct the coated materials from the drum to a desired location.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) in view of Burke et al (US 6,769,381).

The teachings of Velo have been mentioned above but Velo fails to teach or suggest angularly spaced chute like guide elements at the outfeed opening. However, it was known in the art, at the time the invention was made, to provide a plurality of predetermined angularly

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spaced chute like guide elements (84, 85, 86) at the outfeed opening in order to promote reverse tumbling or mixing of materials within the rotary drum or pan with minimal product breakage as evidenced by Burke et al (col. 12, lines 8-31). It would have been obvious to one of ordinary skill in the art to provide predetermined angularly spaced chute like guide elements as taught by Burke et al in the drum of Velo in order to promote reverse tumbling/mixing of the pills or tablets with coating material with minimal breakage of the pills or tablets. Moreover, the use of an appropriate number of chute like elements is within the purview of one skilled in the art to facilitate the tumbling/mixing action.

With respect to the angular intervals between the guide elements being 120 degrees, Burke et al allude to the angular disposition of the guide elements within the rotary drum contributing to more or less tumbling such that one of ordinary skill in the art would determine via experimentation the angular disposition of the guide elements in accordance with the degree of tumbling action required.

Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) in view of Blouin (T927005).

The teachings of Velo have been mentioned above but Velo is silent concerning the infeed opening having an access conduit provided on a protrusion of the pan, the conduit being accessible from outside with an inclined surface that extends therefrom. However, it was known in the art, at the time the invention was made, to provide infeed opening having an access conduit provided on a protrusion of the pan, the conduit being accessible from outside with an inclined surface that extends therefrom as a means to feed particulate materials into a rotary

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drum or pan as evidenced by Blounin (Fig. 2, conduit (6) to angled chute (area above element 16)). It would have been obvious to one of ordinary skill in the art to provide an access conduit provided on a protrusion of the pan, the conduit being accessible from outside with an inclined surface as taught by Blounin in communication with infeed opening of the pan of Velo as a means to feed the pills or tablets into the pan or drum.

With respect to claim 15, Velo is silent concerning the outfeed opening including a tubular conduit leading outside the pan. However, Blounin provides a tubular conduit (5, 8) leading to the outside of the pan to feed pills or tablets out of the pan as shown in Fig. 2. It would have been obvious to one of ordinary skill in the art to provide tubular conduit leading outside as taught by Blounin in the pan of Velo in order to feed the pills or tablets out of the pan.

Claims 10, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) and Itoh et al (EP 0362888) as applied to claim 9 above, and further in view of Dunn Jr. (US 3,606,860) and Gross (US 4,421,020).

The teachings of Velo and Itoh et al have been mentioned above but neither teach or suggest a sealed shutoff valve on the tubular outlet conduit or inlet/access conduit. However, it was known in the art, at the time the invention was made, to provide sealed valving on the inlet and outlet conduits of a pan or drum to control the flow of material therethrough as evidenced by Dunn, Jr. (col. 2, lines 52-58 and col. 3, lines 4-5) and it was known to utilize shutoff valving on inlet and outlet conduits of a drum to control flow or non-flow of material with respect to a drum as evidenced by Gross (col. 6, lines 38-44 and col. 7, lines 45-48). In light of the teachings of both Dunn Jr. and Gross, it would have been within the purview of one skilled in the art to

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provide valving of the shutoff type on the inlet and outlet conduits to the pan or drum of the apparatus defined by the combination above in order to control flow of material introduced into and out from the pan or drum.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) and Blouin (T927005) as applied to claim 8 above, and further in view of Dunn Jr. (US 3,606,860) and Gross (US 4,421,020).

The teachings of Velo and Blouin have been mentioned above but neither teach or suggest a sealed shutoff valve on the tubular outlet conduit or inlet/access conduit. However, it was known in the art, at the time the invention was made, to provide sealed valving on the inlet and outlet conduits of a pan or drum to control the flow of material therethrough as evidenced by Dunn, Jr. (col. 2, lines 52-58 and col. 3, lines 4-5) and it was known to utilize shutoff valving on inlet and outlet conduits of a drum to control flow or non-flow of material with respect to a drum as evidenced by Gross (col. 6, lines 38-44 and col. 7, lines 45-48). In light of the teachings of both Dunn Jr. and Gross, it would have been within the purview of one skilled in the art to provide valving of the shutoff type on the inlet and outlet conduits to the pan or drum of the apparatus defined by the combination above in order to control flow of material introduced into and out from the pan or drum.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) in view of Dunn Jr. (US 3,606,860).

The teachings of Velo have been mentioned above but Velo is silent concerning the infeed opening and outfeed opening being connected to separate reservoirs one for feeding product into the drum and the other for receiving treated product. However, it was known in the art, at the time the invention was made, to provide separate reservoirs one for supply (22) of untreated product and one (area 23) for receipt of treated product as evidenced by Dunn Jr. (col. 2, lines 55-57; col. 3, lines 4-6). It would have been obvious to one of ordinary skill in the art to provide the separate reservoirs as taught by Dunn Jr. in communication with the infeed opening and outfeed opening of the Velo pan in order to supply and collect the tablets or pills.

Claims 16, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velo (EP 0504773) and Blouin (T927005) as applied to claim 15 above, and further in view of Dunn Jr. (US 3,606,860) and Gross (US 4,421,020).

The teachings of Velo and Blouin have been mentioned above but neither teach or suggest a sealed shutoff valve on the tubular outlet conduit or inlet/access conduit. However, it was known in the art, at the time the invention was made, to provide sealed valving on the inlet and outlet conduits of a pan or drum to control the flow of material therethrough as evidenced by Dunn, Jr. (col. 2, lines 52-58 and col. 3, lines 4-5) and it was known to utilize shutoff valving on inlet and outlet conduits of a drum to control flow or non-flow of material with respect to a drum as evidenced by Gross (col. 6, lines 38-44 and col. 7, lines 45-48). In light of the teachings of both Dunn Jr. and Gross, it would have been within the purview of one skilled in the art to provide valving of the shutoff type on the inlet and outlet conduits to the pan or drum of the

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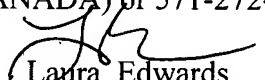
apparatus defined by the combination above in order to control flow of material introduced into and out from the pan or drum.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip Tucker can be reached on (571) 272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Laura Edwards  
Primary Examiner  
Art Unit 1734

Le  
August 24, 2007